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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/785,600

02/23/2004

Bruce W. Kneller

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05/03/2007

LAW OFFICE OF STEVEN B. LEAVITT, L.L.P.

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

05/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/785,600

Applicant(s)

KNELLER, BRUCE W.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

### **First Office Action on the Merits**

#### ***Duplicate Claims***

1. Claims 6, 13, 14 and 20 are objected to under 35 U.S.C. 101 as being a substantial duplicates of claims 5, 7, 8 and 15, respectively. When one claim is allowed, the other claim will be rejected as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The recitation of a property into a compound claim is not considered a further limitation of the claim.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12, 16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of

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the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

Briefly, the instant claims are drawn to a method of improving immune response, neurological condition, symptoms of HIV/AIDS, heart disease etc. and is inclusive of every immune responses, neurological conditions, etc. However, the present specification lacks guidance and/or working examples showing the effect of the claimed compounds in the improvement of any condition. Because of the complexity of the human body and the various conditions encompassed by the instant claims as well as the lack of showing by the present specification of the effect of the claimed compounds in the improvement of any condition, the skilled artisan in the art at the time of the present invention would doubt the claimed compounds would be useful as recited by the instant claims. Therefore, in order to practice the claimed invention, the skilled artisan in the art at the time of the present invention would have to determine the effective of claimed compounds in the improvement of every condition encompassed by the instant claims. Because of the knowledge in the medical art, the quantity of experimentation necessary to practice the claimed invention would be undue.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

Claims 1, 7 and 15 recite "a desired response" but do not define said response.

Therefore, the metes and bound of the claimed invention is unclear.

Claims 5, 7 and 15 recite several compounds wherein =O, i.e., one, is in the  $\beta$  or  $\alpha$  position, for example,  $\Delta$  5-Androstene-7 $\alpha$ -one-3 $\beta$ ,17 $\beta$ -diol. However, the substituent "=O" in the 7-position, is rigid and rotation is impossible, thus, =O cannot be  $\alpha$  or  $\beta$ . It is suggested that said compounds be rewritten deleting reference to  $\alpha$  or  $\beta$ , for example,  $\Delta$  5-Androstene-7-one-3 $\beta$ ,17 $\beta$ -diol.

Claims 12 and 16-19 recite the term "includes" which is an open-ended term.

Therefore, it is unclear what else is intended by the phrase "desired response" and, thus, the metes and bound of the claimed invention is indefinite (see MPEP § 2111.03).

Claims 12 and 16 recites "improved" immune response, neurological condition, etc. The present specification lacks definition of what is intended by "improved" or which conditions, for example, which neurological condition is improved and, thus, the claims are unclear.

Claim 18 recites an improvement in symptoms of one or more ailments.

However, because there are a number of different symptoms associated with each ailment, it is unclear which of said symptoms are improved.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5-8, 12-17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lardy et al. (WO 95/06472).

Lardy et al. teaches  $\Delta$  5-Androstenes such as  $\Delta$  5-Androstene-3 $\beta$ ,7 $\alpha$ -diol-17-one and  $\Delta$  5-Androstene-3 $\beta$ -ol-7,17-dione and their use in promoting weight control (see the entire article, especially Abstract; page 4, lines 3-30; Claims 1-18). The compounds and method taught by the reference are encompassed by the instant claims.

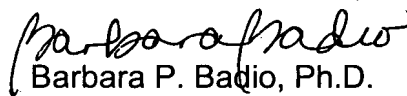
***Telephone Inquiry***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
April 30, 2007